

**Testimony of Ellen Kraig, Ph.D., The American Association of Immunologists,
Submitted to the House Appropriations Subcommittee on Labor, Health and Human
Services, Education and Related Agencies,
Regarding the FY 2008 Budget for the National Institutes of Health
March 29, 2007**

The American Association of Immunologists (“AAI”), a not-for-profit professional society representing more than 6,500 of the world’s leading experts on the immune system, appreciates having this opportunity to submit testimony regarding FY 2008 funding for the National Institutes of Health (NIH). The NIH budget is of great concern to our members - research scientists and physicians who work in academia, government, and industry - many of whom depend on NIH funding to support their work.ⁱ With approximately 83% of NIH’s \$28.9 billion budget awarded to more than 325,000 scientists throughout the United States and around the world, NIH’s funding level drives not only the advancement of immunological and biomedical research, but also the economic activity that fuels local and national economies.ⁱⁱ

Why immunology?

Basic research on the immune system provides a foundation for the discovery of ways to prevent, treat, and cure disease through the development of diagnostics, vaccines, and therapeutics.ⁱⁱⁱ Immunologists use animal models to test theories about immune system function and treatments;^{iv} if successful, treatments are then tested on human subjects through clinical trials before being approved for use by the Food and Drug Administration (“FDA”) and made available to the general population.

Immunological research focuses on many of the diseases that most threaten life and health: infectious diseases like HIV/AIDS, influenza and avian flu, and malaria; and chronic diseases, like diabetes, cancer, and autoimmune diseases. In recent years, immunologists have also been studying the immune response to natural infectious organisms that may be modified for use as agents of bioterrorism, including plague, smallpox, and anthrax. As described below, this crucial work is already bearing fruit.

Recent scientific discoveries: Blockbusters and hope

The past year has brought tremendous advances in vaccine development, with promising results in preliminary clinical trials of a vaccine for HIV/AIDS. The vaccine has been shown to be safe and to stimulate cellular immune responses against HIV in more than half of the subjects. Scientists have also discovered that the chickenpox vaccine can be given to adults in order to prevent the occurrence of painful shingles in later years. The hallmark of recent vaccine research was the final FDA approval of the first vaccine against cancer, a vaccine for HPV (Human Papillomavirus). HPV infects over 8% of women aged 15-50 and can cause cervical cancer; the new vaccine is efficacious both in preventing primary infection and importantly, in reducing the incidence of cervical cancer.

Immunologists have also made novel insights into understanding “innate” or “natural” immune responses (those that do not require immunization or prior exposure) and the role of soluble factors in inflammation; this has helped scientists discover what appears to have made the 1918 influenza strain so deadly. This discovery may lead to more effective life-saving treatments for influenza patients and will also have broader implications for diseases caused by pandemic influenza, other viruses and bacteria. This and other such advances depend on substantial, reliable, and sustained public investment in basic immunological research.

But the NIH budget has gone down, threatening ongoing progress

AAI is very grateful to this subcommittee and the Congress for its successful bipartisan effort to double the NIH budget from FY 1999 to FY 2003. This unprecedented commitment by the federal government to biomedical research allowed scientists to grow the research enterprise, including training new young investigators. *Researchers had begun to capitalize on many important advances that resulted from the budget doubling, leading to increased translational and clinical applications. Unfortunately, this momentum has already been hampered by sub-inflationary budget increases since FY 2003.*^v As a result, although the NIH budget has slightly increased (from \$27.067 billion in FY 2003 to \$28.931 billion in FY 2007), NIH has already lost about 8.5% in purchasing power since FY 2003. This loss in purchasing power, which would grow to about 13.3% if the President's FY 2008 budget were approved,^{vi} is already having a devastating effect:

1. Key NIH Institutes have already had to drop their RO1 paylines to 10-14%, significantly below the approximately 22% funded during the doubling. With funding so low, even outstanding grant applications are not being funded on their first submission, forcing even the most successful senior investigators to spend valuable time on revising and resubmitting their applications.
2. The President's budget would provide no inflationary increases for direct, recurring costs in non-competing Research Project Grants (RPGs), for the 3rd straight year.
3. Although the FY 2007 Joint Funding Resolution provides \$91 million to fund 1500 first-time investigators, the President's FY 2008 budget will either be unable to sustain that promising new effort, or will do so at the expense of funding established investigators.
4. The President's budget would not permit increases in already inadequate stipends and benefits for post-doctoral fellows, whose work is critical to today's established investigators and who will be the principal scientists of tomorrow.

The President's FY 2008 budget would have rapid and long-term adverse repercussions on Americans' health and the national economy: in addition to their terrible human toll, disease and disability cost society trillions of dollars annually in medical care, lost wages and benefits, and lost productivity.^{vii} The President's budget would also jeopardize the future of the biomedical research enterprise: our brightest young people will be deterred from pursuing biomedical research careers if their chances of receiving an NIH grant, or of being able to sustain a career as an NIH-funded scientist, do not improve. If we are unable to attract and retain the best young minds, the United States will lose more of its senior scientists, as well as its preeminence in medical research, science, and technology, to nations (including India, Singapore, and China) that are already investing heavily in this essential economic sector.

AAI recommends a 6.7% budget increase for FY 2008

AAI urges the subcommittee to increase the NIH budget by 6.7% (\$ 1.9 billion) in FY 2008, for a total budget of \$30.8 billion. This increase, which is only 3% above the projected rate of biomedical research inflation,^{viii} would begin to restore the loss in purchasing power that has occurred since the NIH budget doubling ended in FY 2003. (Full restoration of the loss of purchasing power will require that NIH also receive 6.7% increases in FY 2009 and FY 2010.)

Real and immediate threats: influenza and bioterrorism

Seasonal influenza leads to more than 200,000 hospitalizations and about 36,000 deaths nationwide in an average year. Moreover, an influenza pandemic as serious as the one that occurred in 1918 could result in the illness of almost 90 million Americans and the death of more than 2 million, at a projected cost of \$683 billion.^{ix} And yet, while one potential pandemic influenza strain, H5N1 (avian influenza), has already killed more than 150 people around the world, the President's FY 2008 NIH budget will permit NIAID to devote only \$223.2 million to influenza (\$11.5 million more than FY 2007). This is an insufficient increase for the agency with primary responsibility for both the scientific research and clinical trials needed to develop vaccines, antiviral drugs, and diagnostic tools to combat both seasonal and pandemic influenza.^x

AAI is also concerned that the President's FY 2008 NIH budget leaves inadequate funding for biodefense research; the \$1.7 billion allocated represents a net decrease of 0.4% (4.1% after accounting for projected inflation) from FY 2007. Although the availability of non-recurring construction costs will allow NIAID to devote an additional \$17 million to this research, AAI believes that the inadequate increase in NIH funding is restricting research into the human response to the many natural and man-made pathogens that could be used for nefarious purposes.

AAI strongly believes that the best preparation for a pandemic or bioterrorism is to focus on basic research: for a pandemic, the focus should be on seasonal flu, including building capacity, pursuing new production methods (cell based), and seeking optimized flu vaccines and delivery methods. For bioterrorism, the focus should be on identifying new pathogens, understanding the immune response, and developing tools (including new and more potent vaccines) to protect against the pathogen.^{xi}

The new "National Institutes of Health (NIH) Reform Act of 2006"

The NIH Reform Act of 2006 calls for the establishment of a Division of Portfolio Analysis and Strategic Initiatives to better analyze NIH's portfolio, provide leadership and coordination for trans-NIH research initiatives (including the NIH "Roadmap for Medical Research"), and fund new trans-NIH initiatives through a "Common Fund". Although AAI supports this effort to improve NIH analysis and management, AAI urges 1) that the funds allocated to the Common Fund not grow faster than the overall NIH budget, and 2) that all Common Fund awards/grants be awarded through a rigorous peer review process.

The NIH effort to require all grantees to give NIH author manuscripts

AAI strongly opposes any effort to require NIH grantees to submit to NIH manuscripts reporting research funded in whole or in part by NIH. Rather, AAI believes that NIH should partner with not-for-profit scientific publishers to provide public access to NIH-funded research results rather than to duplicate, at great cost to NIH and taxpayers, services which are already provided cost-effectively and well by the private sector. AAI urges the subcommittee to require NIH to work with the not-for-profit scientific publishing community to develop a plan to enhance public access that addresses publishers' concerns, which include ensuring their journals' continued ability to provide high quality, independent peer review of NIH-supported research.

Preserving high quality peer review and ensuring the independence of science

Millions of lives - as well as the prudent use of taxpayer dollars - depend on the independence of scientists and the willingness of government officials to accept the best, most independent scientific advice available. AAI urges this subcommittee to provide oversight which ensures that funds expended enhance the ability of scientists to provide independent scientific advice (particularly on government scientific advisory panels) and to ensure the vigor of peer review, whether through the peer review system at NIH or by supporting the vitality of independent scientific journals which provide independent, expert peer review of taxpayer funded research.

Ensuring NIH operations and oversight

The President's FY 2008 budget proposal for Research, Management and Services (RM&S), which supports the management, monitoring, and oversight of intramural and extramural research activities (including NIH's peer review process), includes a budget of \$1.135 billion, an increase of only \$10 million or .89%. AAI is concerned that this sub-inflationary increase will harm NIH's ability to supervise a portfolio of increasing size and complexity, and to ensure that NIH funds are well and properly spent. AAI urges the subcommittee to explore with NIH management an appropriate increase for this account.

Conclusion

AAI greatly appreciates this opportunity to submit testimony and thanks the members of the subcommittee for their strong support for biomedical research, the NIH, and the scientists who devote their lives to preventing, treating, and curing disease.

ⁱ The majority of AAI members are medical school and university professors and researchers who receive research grants from NIH, and in particular from the National Institute of Allergy and Infectious Diseases (NIAID), the National Cancer Institute (NCI), and the National Institute on Aging (NIA).

ⁱⁱ NIH funding "supports peer-reviewed basic, clinical and translational scientific research at more than 3,000 universities, medical schools, hospitals, and research institutions throughout the 50 states and overseas.... Additionally, NIH supports 6,000 intramural scientists in its own laboratories." FY 2008 Director's Budget Request Statement: Fiscal Year 2008 Budget Request, Witness appearing before the House Subcommittee on Labor-HHS-Education Appropriations, Elias A. Zerhouni, M.D., Director, National Institutes of Health (March 6, 2007)
<http://www.nih.gov/about/director/budgetrequest/fy2008directorsbudgetrequest.htm>

ⁱⁱⁱ The immune system works by recognizing and attacking "foreign invaders" (i.e., bacteria and viruses) inside the body and by controlling the growth of tumor cells. The immune system can protect its host (human or animal) from illness or disease either entirely - by attacking and destroying the virus, bacterium, or tumor cell - or partially, resulting in a less serious illness. A healthy immune system cannot completely protect its host from all threats that might cause disease, and it will reject transplanted organs and bone marrow. Moreover, it can malfunction, allowing the body to attack itself instead of an invader (resulting in an "autoimmune" disease like Type 1 diabetes, multiple sclerosis, or rheumatoid arthritis).

^{iv} Without animal experimentation, immunologists and other researchers would have to use human subjects, an ethically unacceptable alternative. Despite the clear necessity for animal research, scientists continue to be threatened by people and organizations that oppose such research.

^v NIH funding increases since the doubling period ended [FY 2004 (3.03%), FY 2005 (2.18%) and FY 2006 (-.12%)] have all been below the “Biomedical Research and Development Price Index (“BRDPI”), a U.S. Department of Commerce (“DOC”) estimate of the cost of inflation for biomedical research. The BRDPI is updated annually to indicate how much the NIH budget must increase to maintain purchasing power. U.S. Department of Health and Human Services memo dated February 5, 2007: “Biomedical Research and Development Price Index: FY 2006 Update and Projections for FY 2007-2012”
http://officeofbudget.od.nih.gov/PDF/BRDPI_letter_2_5_07.pdf
http://officeofbudget.od.nih.gov/PDF/BRDPI_2_5_07.pdf

^{vi} The President’s FY 2008 budget cuts the NIH budget by \$529 million (including \$200 million to be given to the Global AIDS Fund). See explanation regarding the loss in purchasing power in the report “Within Our Grasp – Or Slipping Away - Assuring a New Era of Scientific and Medical Progress” A Statement by a Group of Concerned Universities and Research Institutions, March 20, 2007

^{vii} National health expenditures (i.e., what the government, health care providers, and patients spend on health care, excluding lost wages/benefits and lost productivity) cost \$3.28 trillion in 2006; they are projected to rise to \$4.1 trillion in 2016. U.S. Department of Health and Human Services - Centers for Medicare and Medicaid Services National Health Expenditure Data
<http://www.cms.hhs.gov/NationalHealthExpendData/downloads/proj2006.pdf>
<http://www.cms.hhs.gov/NationalHealthExpendData/downloads/highlights.pdf>

^{viii} See Footnote 5, *supra*. The BRDPI for FY 2008 is projected to be 3.7%.

^{ix} A report issued by Trust for America’s Health predicts that a severe pandemic flu outbreak could result in the second worst recession in the United States since World War II, resulting in a drop in the U.S. Gross Domestic Product of over 5.5%. The report, “Pandemic Flu and the Potential for U.S. Economic Recession,” was funded by The Pew Charitable Trusts as part of the U.S. Pandemic Preparedness Initiative. The report predicts that people who become ill are likely to take at least 3 weeks to recover, while others would miss work either to care for family members or stay home to avoid exposure to the flu.

^x The Department of Health and Human Services Pandemic Influenza Preparedness and Response Plan gives primary responsibility to NIH, and specifically to NIAID.

^{xi} AAI is concerned that the President’s FY 2008 budget for the Department of Health and Human Services requests only \$211 million for the Biomedical Advanced Research and Development Agency (“BARDA”), a new agency established to foster the translation of NIH research into development of medical and bioterrorism countermeasures. AAI is concerned that if BARDA’s budget is inadequate to support its work, NIH may be forced to assume either duties or costs for BARDA.